K06 1432
1 of 2

SEP 11 2006

510(k) Summary

Name of Submitter:

HOSPIRA, Incorporated
275 North Field Drive
Lake Forest, Illinois 60045
Owner/Operator #: 9063339

Manufacturer and Establishment Registration Number:

Manufacturer:

HOSPIRA LTD.
Carretera Sanchez, km 18 ½
Parque Industrial Itabo, S.A.
Haina, San Cristobal, Dominican Republic

Establishment Registration #: 9613251

Proprietary or Trade Name of Proposed Device: Hospira® Enteral Feeding Sets

Common Name: Enteral Bag w/Pump Set

Device Classification, Pancode and ProCode: Class II, 80-KNT

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Infusion pumps. Tubes, gastrointestinal (and accessories) are regulated within 21 CFR 880.5860.

Intended Use / Indications for Use:
The HOSPIRA® Enteral Feeding Sets is intended to deliver, via gravity or a pump, liquid nutrition formulas to an enteral access device (a feeding tube).

Proposed Device Description:
The HOSPIRA® Enteral Feeding Sets will consist of variations of the following components: non-DEHP Enteral feeding bags, non-DEHP plasticized polyvinyl tubing, fluid shut off devices, non-DEHP sight chambers, cassette technology and adapters for enteral feeding catheters.

Summary of Substantial Equivalence

The HOSPIRA® Enteral Feeding Sets as described in this submission is substantially equivalent to the primary predicate device Enteral Pump Set with Integral Container (K810996 & K052052) with respect to the following:

Similarities:

1) Both devices are intended to temporarily hold and deliver nutritional fluids from a container to a patient's enteral access site
2) The operating principles are the same for both devices
3) Both primary labeling and device bags clearly state not for I.V. or Epidural Use

Difference:

1)The HOSPIRA® Enteral Feeding Sets will be comprised of all non-DEHP materials.
2)The HOSPIRA® Enteral Feeding Sets will contain a non-PVC enteral feeding bag.

The HOSPIRA® Enteral Feeding Sets as described in this submission is substantially equivalent to the secondary predicate device I.V. Set with Single Channel Cassette (K865059 & K052052) with respect to the following:

Similarities:

1) Both use the same infusion cassette technology
2) The operating principles are the same for both devices.

Difference:

1) The predicate is cleared for I.V. use, the subject is for enteral use
3) The HOSPIRA® Enteral Feeding Sets will contain a non-PVC enteral feeding bag.
4) The HOSPIRA® Enteral Feeding Sets will be comprised of all non-DEHP materials.

Statement of Safety and Effectiveness

The HOSPIRA® Enteral Feeding Sets meets the functional claims and intended use as described in the product labeling, and is as safe and effective in terms of substantial equivalence as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 11 2006

Ms. Diane Rennpferd
Sr. Associate, Global Regulatory Affairs – Devices
Hospira, Inc.
Department 0389, Bldg. H2
275 North Field Drive
LAKE FOREST IL 60045

Re: K061432
Trade/Device Name: HOSPIRA® Enteral Feeding Sets
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: July 20, 2006
Received: July 21, 2006

Dear Ms. Rennpferd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K061432

Indications for Use

510(k) Number (if known)

Device Name: **HOSPIRA® Enteral Feeding Sets**

Indications for Use:

The Hospira® Enteral Feeding Sets is intended to deliver, via gravity or a pump, liquid nutrition formulas to an enteral access device (a feeding tube).

Prescription Use __X__ AND/OR **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Krause

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061432